WHAT IS CLAIMED IS:

5

10

15

20

- 1. A non-human transgenic organism comprising a transgenic element that engenders therein production of a prothrombin or prothrombin-related polypeptide.
- 2. A transgenic organism according claims 1 wherein the transgenic organism is a non-human mammal.
 - 3. A transgenic organism according to claim 2, wherein the mammal is mouse, rat, hamster, rabbit, pig, sheep, goat, cow or horse.

A transgenic organism according to claim 3, wherein the mammal is pig.

- 5. A transgenic organism according to claim 1, wherein the prothrombin or prothrombin-related polypeptide therein produced accumulates in a specific tissue, compartment, fluid or product of the transgenic organism.
 - 6. A transgenic organism according claims 5, wherein the transgenic organism is a non-human mammal.
- 7. A transgenic organism according to claim 6, wherein the mammal is mouse, rat, hamster, rabbit, pig, sheep, goat, cow or horse.
 - 8. A transgenic organism according to claim 6, wherein the organism is female and the polypeptide accumulates in milk.
 - 9. A transgenic organism according to claim 8, wherein the mammal is mouse, rat, hamster, rabbit, pig, sheep, goat, cow or horse.

10. A transgenic organism according to claim 9, wherein the mammal is pig.

546 Q1 11. A transgenic organism according to any of claims 1 through 10, wherein

the prothrombin or prothrombin-related polypeptide-produced in the organism when isolated and purified has a specific activity is 75% to 125% of that of purified human prothrombin.

- 12. A transgenic organism according to claim 11, wherein activity is determined by a chromogenic assay of amidolytic activity or by APTT assay.
- the prothrombin or prothrombin related polypeptide comprises a region having an amino acid sequence 80% to 100% identical to that of a mammalian thrombin.
- 14. A transgenic organism according to claim 13, wherein the prothrombin or prothrombin-related polypeptide produced in the organism when isolated and purified has a specific activity is 75% to 125% of that of purified human prothrombin.
 - 15. A transgenic organism according to claim 14, wherein the mammalian thrombin is human thrombin.
- or prothrombin-related polypeptide comprises a region having the amino acid sequence of human thrombin.
 - 17. A transgenic organism according to any of claims 1 through 10, where in the prothrombin or prothrombin related polypeptide comprises a region having an amino acid sequence 80% to 100% identical to that of a mammalian prothrombin.
- 20 18. A transgenic organism according to claim 17, wherein the prothrombin or prothrombin-related polypeptide produced in the organism when isolated and purified has a specific activity is 75% to 125% of that of purified human prothrombin.
 - 19. A transgenic organism according to claim 18, wherein the mammalian prothrombin is human prothrombin.

5

10

15

20

25

looussys loseroe

- 50 0 0 20. A transgenic organism according to claim 19, wherein the prothrombin or prothrombin-related polypeptide comprises a region having the amino acid sequence of human prothrombin.
 - 21. A transgenic organism according to claim 20, wherein activity is determined by a chromogenic assay of almitolytic activity or by APTT assay.
 - 22. A transgenic organism according to claim 11 wherein the transgenic element comprises a promoter operatively linked to a region encoding prothrombin or a prothrombin-related polypeptide, wherein further the promoter is selected from the group consisting of the promoters of whey acidic protein genes, casein genes, lactalbumin genes and beta lactoglobulin genes.
 - 23. A transgenic organism according to claim 14, wherein the transgenic element comprises a promoter operatively linked to a region encoding prothrombin or a prothrombin-related polypeptide, wherein further the promoter is selected from the group consisting of the promoters of whey acidic protein genes, casein genes, lactalbumin genes and beta lactoglobulin genes.
 - 24. A transgenic organism according to claim 17, wherein the transgenic element comprises a promoter operatively linked to a region encoding prothrombin or a prothrombin-related polypeptide, wherein further the promoter is selected from the group consisting of the promoters of whey acidic protein genes, casein genes, lactalbumin genes and beta lactoglobulin genes.
 - A transgenic organism according to claim 11, wherein the promoter is the 25. mouse long whey acidic protein promoter.
 - 26. A transgenic organism according to claim 14, wherein the promoter is the mouse long whey acidic protein promoter.
 - 27. A transgenic organism according to claim 17, wherein the promoter is the

15

mouse long whey acidic protein promoter.

- 28. A prothrombin or prothrombin-related polypeptide isolated from a transgenic organism.
- 29. A prothrombin or prothrombin-related polypeptide isolated from a transgenic organism that differs in its post-translational modification from naturally occurring prothrombin polypeptides.
 - 30. A prothrombin or prothrombin-related polypeptide according to claim 29 that differs from naturally occurring prothrombins in any one or combination of its glycosylation, γ-carboxylation or activation by proteolytic processing.
- 31. A prothrombin or prothrombin-related polypeptide according to any of claims 28 through 30 having a specific activity is 75% to 125% of that of purified human prothrombin.
 - 32. A prothrombin or prothrombin-related polypeptide according to claim 31, wherein activity is determined by a chromogenic assay of amidolytic activity or by APTT -assay.
 - 33. A prothrombin or prothrombin-related polypeptide according to claim 31, wherein the prothrombin or prothrombin related polypeptide comprises a region having an amino acid sequence 80% to 100% identical to that of a mammalian thrombin.
- 34. A prothrombin or prothrombin-related polypeptide according to claim 33, wherein the mammalian thrombin is human thrombin.
- wherein the prothrombin or prothrombin-related polypeptide according to claim 34, wherein the prothrombin or prothrombin-related polypeptide comprises a region having the amino acid sequence of human thrombin.

PCT/US00/22616

- 36. A prothrombin or prothrombin-related polypeptide according to claim 31, wherein the prothrombin or prothrombin related polypeptide comprises a region having an amino acid sequence 80% to 100% identical to that of a mammalian prothrombin.
- 37. A prothrombin or prothrombin-related polypeptide according to claim 36,
 5 wherein the mammalian prothrombin is human prothrombin.
- wherein the prothrombin or prothrombin-related polypeptide according to claim 37, wherein the prothrombin or prothrombin-related polypeptide comprises a region having the amine acid sequence of human prothrombin.
- 39. A prothrombin or prothrombin-related polypeptide according to claim 38, wherein activity is determined by a chromogenic assay of amidolytic activity or by APTT assay.
 - 40. A composition comprising a prothrombin or a prothrombin-related polypeptide produced in a transgenic organism.
 - 41. A composition according to claim 40, wherein the prothrombin or prothrombin-related polypeptide differs in its post-translational modification from naturally occurring prothrombin polypeptides.

15

20

- 42. A composition according to claim 41, wherein the prothrombin or prothrombin-related polypeptide differs from naturally occurring prothrombins in any one or combination of its glycosylation, γ-carboxylation or activation by proteolytic processing.
- 43. A composition according to claim 43, wherein the prothrombin or prothrombin-related polypeptide has a specific activity 75% to 125% of that of purified human prothrombin.
 - 44. A composition according to claim 43, wherein the prothrombin or

-60-

prothrombin related polypeptide comprises a region having an amino acid sequence 80% to 100% identical to that of a mammalian thrombin.

- 45. A composition according to claim 44, wherein the mammalian thrombin is burnan thrombin.
- prothrombin-related polypeptide comprises a region having the amino acid sequence of human thrombin.
 - 47. A composition according to claim 43, wherein the prothrombin or prothrombin-related polypeptide is human prothrombin.
- 10 48. A composition according to claim 47, wherein the prothrombin or prothrombin-related polypeptide comprises a region having the amino acid sequence of human prothrombin.
 - 49. A composition according to claim 48, wherein, wherein activity is determined by a chromogenic assay of amidolytic activity or by APTT assay.
- 15 50. A composition according to claim 40, wherein the prothrombin or prothrombin-related polypeptide is produced in milk of a non-human transgenic female mammal.
 - 51. A composition according to claim 50, wherein the composition is milk of the transgenic mammal.
- 20 52. A composition according to claim 50, herein the composition is derived from milk of the transgenic mammal.
 - 53. A method for treating a wound in a patient comprising a step of administering to said patient a composition according to any of claims 40 through 49

5

-61-

- 54. A method for treating a wound in a patient comprising the step of contacting the wound with a composition according to any of claims 40 through 49.
- 55. A method for producing a prothrombin or a prothrombin-related polypeptide comprising expressing the prothrombin or prothrombin-related polypeptide in a transgenic organism and isolating from the transgenic organism the prothrombin or prothrombin-related polypeptide.